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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,351	03/12/2004	Detlef Becker	P03,0116-01	9892
7590 SCHIFF HARDIN LLP Patent Department 6600 Sears Tower 233 South Wacker Drive Chicago, IL 60606				
04/28/2009				
EXAMINER				
KAMAL, SHAHID				
ART UNIT		PAPER NUMBER		
3621				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,351

Applicant(s)

BECKER ET AL.

Examiner

SHAHID KAMAL

Art Unit

3621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgements

1. Claims 38 are remain pending and have been examined.
2. This Office Action is responsive to the amendment filed on February 06, 2009.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchosky (US Pub. No. 2003/0050803 A1) ("Marchosky") in view of Hotchkiss et al. (US Pub. No.: 2003/0140043 A1) ("Hotchkiss").

5. Referring to claim 38, Marchosky discloses the following:
 - a) providing a separate application data (records 112) store containing said patient related electronic data objects (records 112), each electronic data object (records 112) having an associated data object (records 112) identifier to at least one of form structural connections of the data object (records 112) to groups, teams, or references to people, form contextual associations of the data object (records 112) with subject areas or studies, or form affiliation of

the data object (records 112) with clinical studies, diagnostic findings, or with diagnostic image types (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086);

b) providing a separate user (user/¶0054) group store for association of a plurality of unique medical field user (user/¶0054) IDs dependent on previously determined information for identification and authentication of the medical field users (user/¶0054) (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086);

c) providing an access control module connected to access said access right store, said data object (records 112) category store, and said user (user/¶0054) group store and which monitors and controls data accesses by said medical field users (user/¶0054) to said data objects in said data application store, said access control module determining a medical field user (user/¶0054) ID from the user group store, and using said medical field user (user/¶0054) ID, determining an access right category via said access right store, and via access to said data object (records 112) category store, said access control module determining, using said data object (records 112) identifiers, which access right category is associated with the data object (records 112) which the medical field user (user/¶0054) is attempting to access (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086).

Marchosky does not expressly disclose providing a separate data object category store for association of said data object identifiers with access right categories; providing a separate access right store for associating said medical field user IDs with said access right categories so that it can be determined for a particular medical field user the type of access allowed for the particular medical field user for reading, changing, or deleting information contained in the data objects.

Hotchkiss discloses providing a separate data object category store for association of said data object identifiers with access right categories (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219); providing a separate access right store for associating said medical field user IDs with said access right categories so that it can be determined for a particular medical field user the type of access allowed for the particular medical field user for reading, changing, or deleting information contained in the data objects (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219).

Therefore, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified of Marchosky for a record system with the features of Hotchkiss for a clinical research data management system and method in order to access this function, the user must login to the system and must have the appropriate role and associated rights to act as a registrar.

Examiner's Note:

6. The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Response to Arguments

7. Applicant's arguments filed on February 06, 2009 have been fully considered but they are not persuasive.
8. As per claims 38, Applicant argues "Marchosky does not disclose providing a separate application data store containing said patient related electronic data objects, each electronic data object having an associated data object identifier to at least one of form structural connections of the data object to groups, teams, or references to people, form contextual associations of the data object with subject areas or studies, or form affiliation of the data object with clinical studies, diagnostic findings, or with diagnostic image types; providing a separate user group store for association of a plurality of unique medical field user IDs dependent on previously determined information for identification and authentication of the medical field users; providing an access control module connected to access said access right store, said data object category store, and said user group store and which monitors and controls data accesses by said medical field users to said data objects in said data application store, said access control module determining a medical field user ID from the user group store, and using said medical field user ID, determining an access right category via said access right store, and via access to said data object category store, said access control module determining, using said data object identifiers, which access right category is associated with the data object which the medical field user is attempting to access and Hotchkiss does not expressly disclose providing a separate data object category store for association of said data object identifiers with access right categories; providing a separate access right store for associating said medical field user IDs with said access right categories so that it can be determined for a particular medical field user the type of

access allowed for the particular medical field user for reading, changing, or deleting information contained in the data objects (response pages 4-7)".

9. Landry teaches providing a separate application data (records 112) store containing said patient related electronic data objects (records 112), each electronic data object (records 112) having an associated data object(records 112) identifier to at least one of form structural connections of the data object (records 112) to groups, teams, or references to people, form contextual associations of the data object (records 112) with subject areas or studies, or form affiliation of the data object (records 112) with clinical studies, diagnostic findings, or with diagnostic image types (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086); providing a separate user (user/¶0054) group store for association of a plurality of unique medical field user (user/¶0054) IDs dependent on previously determined information for identification and authentication of the medical field users (user/¶0054) (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086); providing an access control module connected to access said access right store, said data object (records 112) category store, and said user (user/¶0054) group store and which monitors and controls data accesses by said medical field users (user/¶0054) to said data objects in said data application store, said access control module determining a medical field user (user/¶0054) ID from the user group store, and using said medical field user (user/¶0054) ID, determining an access right category via said access right store, and via access to said data object (records 112) category store, said access control module determining, using said data object (records 112) identifiers, which access right category is associated with the data object (records 112) which the medical field user (user/¶0054) is attempting to access (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086) and Hotchkiss teaches providing a separate data object category store for association of said data

object identifiers with access right categories (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219); providing a separate access right store for associating said medical field user IDs with said access right categories so that it can be determined for a particular medical field user the type of access allowed for the particular medical field user for reading, changing, or deleting information contained in the data objects (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219);

Conclusion

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahid Kamal whose telephone number is (571) 270-3272. The examiner can normally be reached on MONDAY through THURSDAY between the hours of 8:30 AM and 7 PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Fischer can be reached on (571) 272-6779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for Regular/After Final Actions and 571-273-6714 for Non-Official/Draft.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

15. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SK
April 23, 2009

/EVENS J. AUGUSTIN/

Primary Examiner, Art Unit 3621